

NOT FOR PUBLICATION

FILED UNDER SEAL

**UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY**

ALTANA PHARMA AG and WYETH, Plaintiffs, v. TEVA PHARMACEUTICALS USA, INC., et al., Defendants.	Civil Action No. 04-2355 (JLL) OPINION
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LINARES, District Judge.

This matter comes before the Court by way of Defendants' motion for partial summary judgment seeking a ruling that Nycomed is not entitled to recover lost profits damages as a matter of a law and that its recovery is, instead, limited to an award of reasonable royalty pursuant to 35 U.S.C. § 284 [Docket Entry No. 1126]. The Court has considered the submissions made in support of and in opposition to the instant motion. No oral argument was heard. Fed. R. Civ. P. 78. Based on the reasons that follow, Defendants' motion is **granted**.

BACKGROUND

1. *General*

This is a patent infringement action to enforce United States Patent No. 4,758,579 ("the '579 patent"). The asserted claims of the '579 patent – claims 22 and 25 – cover a chemical compound named Pantoprazole, and its sodium salt, pantoprazole sodium. Pantoprazole is the

active ingredient in PROTONIX®, a drug manufactured for the treatment of gastric acid disorders (hereinafter referred to as “Protonix”). Plaintiff Nycomed GmbH (formerly known as Altana Pharma AG and, at the time of the invention, Byk Gulden) owns the ‘579 patent. Plaintiff Wyeth (formerly known as American Home Products Corporation) markets and sells Protonix in the United States as Nycomed’s exclusive licensee.

Protonix was approved by the FDA on February 2, 2000 and was first marketed to the public in 2000. Defendants Teva, Sun and KUDCo each filed an Abbreviated New Drug Application (“ANDA”) pursuant to the Hatch–Waxman Act, seeking FDA approval to sell a generic version of Protonix prior to the expiration of the ‘579 patent.

In May of 2004, Plaintiffs responded by suing Teva, Sun and KUDCo for infringement of the ‘579 patent. In addition to seeking equitable relief, Plaintiffs seek lost profits damages and/or reasonable royalty damages pursuant to 35 U.S.C. §284.

Plaintiffs’ motion for a preliminary injunction was denied in September 2007. Defendants Teva and Sun subsequently launched generic pantoprazole products “at risk,” i.e., before entry of final judgment on the merits of this litigation, and before the patent expired. Sun, Teva and KUDCo each stipulated to infringement of claims 22 and 25 of the ‘579 patent *if* those claims were ultimately found to be valid and enforceable.

A jury trial was conducted for several weeks in April 2010 with respect to Defendant Teva and Defendant Sun’s affirmative defenses and counterclaims that Claims 22 and 25 of the ‘579 patent are invalid for obviousness and obviousness-type double patenting. Simultaneously, a non-jury trial was conducted with respect to Defendant KUDCo’s affirmative defenses and counterclaims. The jury returned a verdict in favor of Plaintiffs as to each issue tried. On July 15, 2010, the Court issued a bench opinion as to Defendant KUDCo. The Court ruled that

KUDCo had not demonstrated by clear and convincing evidence that the asserted claims of the '579 patent are invalid either for obviousness under 35 U.S.C. § 103 or under the judicially created doctrine of obviousness-type double patenting. The parties subsequently began discovery on the remaining issues in the case—damages and Defendants' claims of unenforceability.

The '579 patent expired on July 19, 2010. The FDA awarded Wyeth a period of pediatric exclusivity that expired on January 19, 2011.

2. *Defendants' Motion*

Defendants Teva and Sun now move for summary judgment on the issue of Nycomed's entitlement to lost profits damages. Defendants maintain that Nycomed is not entitled to lost profits damages because it never sold a product that competed with Defendants' product. In particular, Defendants argue that: (1) to recover lost profits damages, a patentee must show that its product and the infringer's product compete against each other in the same market, (2) Nycomed sold pantoprazole compound to Wyeth who then, pursuant to a License Agreement, manufactured and sold the finished dosage form pantoprazole tablets that Defendants sold, (3) thus, only Wyeth—not Nycomed—may seek lost profits damages in this case. Nycomed opposes Defendants' motion on the basis that its profits depended on the sales of Wyeth, who indisputably made all its sales in the same market as Defendants' infringing sales.

A. *Facts Relevant to Defendants' Motion*

Plaintiff Nycomed owns the '579 patent (SAF, ¶ 1),¹ which, as previously stated, covers, *inter alia*, a chemical compound named pantoprazole—the active ingredient in Protonix. The

¹ "SAF" refers to Plaintiffs' Statement of Additional Facts.

Protonix NDA, which is in Wyeth's name, authorizes Wyeth to sell finished dosage form tablets containing the API pantoprazole sodium powder and other ingredients encased within an enteric tablet coating. (SUMF,² ¶¶ 8-9; RSUMF,³ ¶¶ 8-9). Nycomed holds neither an NDA nor an ANDA to sell any pantoprazole "drug products" in the United States, as that term is defined in 21 C.F.R. § 314(b). (SUMF, ¶ 10; RSUMF, ¶ 10). Rather, in 1997, Wyeth and Nycomed entered into a License Agreement wherein Nycomed granted Wyeth an exclusive license to market and sell pantoprazole in the United States. (SAF, ¶¶ 3-4).

Pursuant to the parties' agreement, Nycomed would sell certain pantoprazole sodium products to Wyeth. (SUMF, ¶ 11; RSUMF, ¶ 11). Some pantoprazole tablets were then manufactured by Nycomed, while others were manufactured by Wyeth (and/or its subsidiary). (SUMF, ¶ 13; RSUMF, ¶ 13). Wyeth ultimately sold the finished dosage form pantoprazole tablets in the United States. (SUMF, ¶ 17; RSUMF, ¶ 17). In exchange, and pursuant to the License Agreement, Nycomed would receive a royalty from Wyeth equal to 25% of the Wyeth's net sales of pantoprazole products. (SAF, ¶5) (W00532203).

LEGAL STANDARD

1. *35 U.S.C. § 284*

Damages in patent infringement cases are governed by 35 U.S.C. § 284, which provides:

Upon finding for the claimant the court shall award the claimant damages adequate to compensate for the infringement, but in no event less than a reasonable royalty for the use made of the invention by the infringer, together with interest and costs as fixed by the court.

² "SUMF" refers to Defendants' Statement of Undisputed Material Facts.

³ "RSUMF" refers to Plaintiff's Response to Defendants' Statement of Undisputed Material Facts.

35 U.S.C. § 284. “Thus, the language of the statute is expansive rather than limiting. It affirmatively states that damages must be adequate, while providing only a lower limit and no other limitation.” *Rite-Hite Corp. v. Kelley Co., Inc.*, 56 F.3d 1538, 1544 (Fed. Cir. 1995). The United States Supreme Court has clarified that, in enacting § 284, “Congress sought to ensure that the patent owner would in fact receive full compensation for ‘any damages’ he suffered as a result of the infringement.” *Gen. Motors Corp. v. Devex Corp.*, 461 U.S. 648, 654-655 (1983).

Generally speaking, the availability of lost profits is a question of law. *Mars, Inc. v. Coin Acceptors, Inc.*, 527 F.3d 1359, 1365 (Fed. Cir. 2008). However, “the correct measure of damages is a highly case-specific and fact-specific analysis.” *Id.* at 1366; *see generally Rite-Hite*, 56 F.3d at 1546 (“[T]he question of legal compensability is one ‘to be determined on the facts of each case upon mixed considerations of logic, common sense, justice, policy and precedent.’ ”).

To recover lost profits damages, “the patentee must show a reasonable probability that, ‘but for’ the infringement, it would have made the sales that were made by the infringer.” *Rite-Hite*, 56 F.3d at 1545. The “but for” inquiry “requires a reconstruction of the market, as it would have developed absent the infringing product,” in order to determine what the patentee would have made. *Grain Processing Corp. v. Am. Maize-Prods. Co.*, 185 F.3d 1341, 1350 (Fed. Cir. 1999). One way to establish “but for” causation is to meet the four-part test pronounced in *Panduit Corp. v. Stahl Bros. Fibre Works*, 575 F.2d 1152, 1156 (6th Cir. 1978). *Kearns v. Chrysler Corp.*, 32 F.3d 1541, 1551 (Fed. Cir. 1994). To recover under the *Panduit* test, the patent owner must prove:

- (1) a demand for the patented product,
- (2) an absence of acceptable noninfringing substitutes,
- (3) manufacturing and marketing capability to exploit the demand, and
- (4) the amount of profit the patent owner would have made.

Id.; but see *Rite-Hite*, 56 F.3d at 1548 (“*Panduit* is not the *sine qua non* for proving ‘but for’ causation. If there are other ways to show that the infringement in fact caused the patentee’s lost profits, there is no reason why another test should not be acceptable.”).

As a threshold matter, however, the Federal Circuit has made clear that the “patentee needs to have been selling some item, the profits of which have been lost due to infringing sales, in order to claim damages consisting of lost profits.” *Poly-America, L.P. v. GSE Lining Tech.*, 383 F.3d 1303, 1311-12 (Fed. Cir. 2004).

2. *Federal Rule of Civil Procedure 56*

Summary judgment is appropriate when, drawing all reasonable inferences in the non-movant’s favor, there exists no genuine issue of material fact and the movant is entitled to judgment as a matter of law. See Fed. R. Civ. P. 56(c); *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 255 (1986); *King Pharm., Inc. v. Eon Labs, Inc.*, 616 F.3d 1267, 1273 (Fed. Cir. 2010).

With this framework in mind, the Court turns now to Defendants’ motion.

ANALYSIS

There is no dispute that Wyeth’s lost sales may have caused harm to Nycomed. See *Mars, Inc. v. Coin Acceptors, Inc.*, 527 F.3d 1359, 1365 (Fed. Cir. 2008). The dispute at issue is simply whether that harm is compensable under a lost profits theory. Thus, the *sole* issue before the Court is whether Nycomed is precluded, as a matter of law, from seeking lost profits damages in this action.⁴

⁴ Even if the Court finds that Nycomed is not legally entitled to recover lost profits damages, there is no dispute that it would be entitled to recover a royalty for Teva’s and Sun’s infringing use of the patent-in-suit. See Def. Br. at 13; 35 U.S.C. § 284.

The Court begins by noting the two most relevant factors, neither of which are in dispute: (1) Nycomed never sold finished dosage form pantoprazole “drug products”—the products that Defendants ultimately sold—in the United States;⁵ and (2) Nycomed is seeking lost profits damages based upon the sales made by Wyeth, its exclusive licensee.⁶

The following relevant legal principles are also undisputed: (1) to recover lost profits damages, the patentee must show a reasonable probability that, “but for” the infringement, it would have made the sales that were made by the infringer;⁷ (2) meeting the *Panduit* test is one way to establish “but for” causation, but it is not the only way;⁸ and (3) regardless of what test is used, in order to claim damages consisting of lost profits, a patentee must demonstrate—as a threshold matter—that it sold an item, the profits of which have been lost due to the sale of the infringing product.⁹

Defendants’ motion for partial summary judgment rests on this last legal principle—the threshold element of direct competition. *See generally Poly-America*, 383 F.3d at 1311. Defendants maintain that Nycomed is not entitled to lost profits damages because it sold no product that competed directly with Defendants’ pantoprazole tablets. This fact is, to a certain

⁵ (SUMF, ¶ 10; RSUMF, ¶ 10); (SUMF, ¶ 17; RSUMF, ¶ 17).

⁶ *See* Pl. Opp’n Br. at 1 (“Wyeth sold pantoprazole in the United States under the ‘579 patent from which [Nycomed] earned profits in the form of royalties on those sales. Thus, [Nycomed’s] profits depended on the sales of Wyeth, who indisputably made all its sales in the same market as Defendants’ infringing sales, thus fulfilling the *Panduit* competition requirement.”); (SAF, ¶5).

⁷ *See Rite-Hite*, 56 F.3d at 1545.

⁸ *See Rite-Hite*, 56 F.3d at 1548.

⁹ *See Poly-America, L.P. v. GSE Lining Tech.*, 383 F.3d 1303, 1311 (Fed. Cir. 2004) (“The patentee needs to have been selling some item, the profits of which have been lost due to infringing sales, in order to claim damages consisting of lost profits.”).

extent, undisputed. *See, e.g.*, SUMF, ¶ 17; RSUMF, ¶ 17 (explaining that Wyeth ultimately sold the finished dosage form pantoprazole tablets in the United States). Thus, the real issue before the Court is whether—notwithstanding the fact that Nycomed did not *itself* sell the product that competed with Defendants’ infringing product—Nycomed has come forward with evidence upon which a reasonable juror could find that it has nonetheless suffered lost profits from the infringement. Based on the reasons that follow, the Court finds that Nycomed has failed to meet this burden.

Nycomed opposes Defendants’ motion on the theory that, by virtue of the License Agreement, its profits depended on Wyeth’s sales; thus, a portion of Wyeth’s lost profits were inherently lost profits of Nycomed. (Pl. Opp’n Br. at 1, 4); (SAF, ¶ 17).¹⁰ Admittedly, however, Nycomed’s position is based *entirely* on its royalty arrangement with Wyeth, pursuant to which Wyeth agreed to pay Nycomed a royalty equal to 25% of Wyeth’s net sales of pantoprazole products. *See* SAF, ¶ 5 (“The exclusive license granted by [Nycomed] to Wyeth to market and sell pantoprazole in the United States was made in consideration for a royalty from Wyeth equal to 25% of Wyeth’s net sales of pantoprazole products.”); SAF, ¶ 10 (“After Defendants’ infringement of the ‘579 patent and Wyeth’s responsive release of Wyeth’s OG, Wyeth and [Nycomed] agreed that Wyeth would pay [Nycomed] a royalty of 36% of Wyeth’s OG sales in the United States (after certain adjustments and deductions).”); SAF, ¶ 17 (“For every dollar of sales lost by Wyeth in the form of lost sales or price erosion on actual sales, Altana lost at least \$0.25 in royalties.”).

Apart from these royalty payments, Nycomed has identified no record evidence that it ever received or recognized any form of profit or revenue from Wyeth. In light of the foregoing,

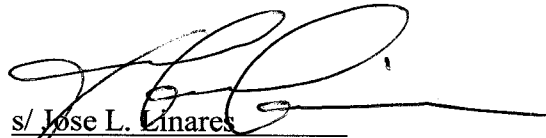
¹⁰ *See, e.g.*, Ruiz Decl., Ex. 63, Vellturo Report, Exs. 30-31.

the Court finds that lost profits damages are not, as a matter of law, available to Nycomed. *See, e.g., Mars*, 527 F.3d at 1367 (affirming district court's finding that patent holder was not entitled to lost profit damages based on the sales of its subsidiary where the evidence revealed simply a "traditional royalty-bearing" arrangement between the two entities); *Poly-America*, 383 F.3d at 1311 ("Awarding lost profits to Poly-America on the basis of its private arrangement with Poly-Flex would synthetically create lost profits for Poly-America, when it may not have suffered any, to the detriment of GSE."). Damages to Nycomed should, instead, be determined on the basis of a reasonable royalty. *See generally Kearns*, 32 F.3d at 1551-1552; 35 U.S.C. § 284. Defendants' motion for partial summary judgment on this issue is, therefore, granted.

CONCLUSION

For the reasons set forth above, Defendants' motion for partial summary judgment seeking a ruling that Nycomed is not entitled to recover lost profits damages as a matter of a law and that its recovery is, instead, limited to an award of reasonable royalty pursuant to 35 U.S.C. § 284 [Docket Entry No. 1126] is **granted**.

An appropriate Order accompanies this Opinion.


s/ Jose L. Linares
Jose L. Linares
United States District Judge

Date: November 5, 2012